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K963633

PREMARKET NOTIFICATION [510(k)] SUMMARY**August 12, 1996**

VitalCom Contact Person: Mr. Ray Pizinger**Trade Name:** VentNet
Common Name: Central Monitoring Station
Classification Name: Monitor, breathing frequency**Trade Name:** NSMS-900
Common Name: Transmitters and Receivers
Classification Name: Transmitters and Receivers, Physiological Signal, Radiofrequency**Substantially Equivalent to:** Spacelabs PCMS Monitor, Model 90845 (K913038)
Spacelabs Flexport Interface, Model 90436-01 (K903702)

SUMMARY OF VENTNET**INTENDED USE****9A. PURPOSE AND FUNCTION OF DEVICE**

The VentNet system consists of a PC based Central Monitoring Station and either a hardwire or wireless communication means allowing the remote monitoring of up to 24 continuous mechanical ventilators. VentNet further has a means of communication via paging system for the remote notification of alarms or changes in ventilator status. The VentNet automatically records ventilator setting changes and alarm events with patient physiological data from the monitored ventilators. The user may then review this information in a ventilator flowsheet format or print it as pre-formatted reports.

VentNet's intended use is to supplement the operation of dispersed or remotely located mechanical ventilators. VentNet allows the remote monitoring of multiple ventilators from a central station. VentNet displays ventilator settings, ventilator alarm status and physiological patient information as communicated from the monitored mechanical ventilator. VentNet also includes an optional feature which causes automatic notification, via paging system to defined users of certain ventilator alarms. VentNet is not intended to replace on-hand competent medical staff in monitoring for, or responding to ventilator alarms but is intended to support that staff by notifying other respiratory care staff or ventilator specialists in the event of certain alarm conditions.

VentNet's secondary intended use is the automation of some of the record keeping and reporting functions performed during mechanical ventilation.

9B. INTENDED PATIENT POPULATION

The intended population are those patients who are being ventilated by the 7200 Series Ventilator.

9C. INTENDED ENVIRONMENT OF USE

The VentNet is intended to be used in an environmentally controlled hospital and hospital type environment.

9D. DEVICE CLAIMS

9D1. ADVERTISING CLAIMS

- 9D1.1) VentNet can be installed as either a hardwire system which can monitor up to sixteen (16) 7200 Series Ventilators or an FCC approved radio system which can monitor up to twenty-four (24) 7200 Series Ventilators.
- 9D1.2) From a VentNet central monitoring station a user can remotely monitor ventilator settings, alarm status, and physiological patient information for up to 24 7200 Series Ventilators.
- 9D1.3) VentNet uses established graphical user interface conventions to improve ease of learning and operation for operators familiar with Windows software applications. The VentNet system can be installed to operate either with a mouse or with a touch screen.
- 9D1.4) VentNet is compatible with Nellcor Puritan-Bennett 7200 Series Ventilator supporting the host port or DCI communications option or with future Nellcor Puritan-Bennett continuous critical care ventilators which support the same communications protocols.
- 9D1.5) VentNet automatically records ventilator settings and ventilator alarm events for monitored ventilators and displays that information in a spreadsheet format for review. VentNet will record the most recent events, up to 1000 records, as they occur. The time and date of settings changes and alarm events are automatically recorded to allow a chronological history. Physiological patient information is recorded along with the alarm events to assist the user in understanding the alarm event.

- 9D1.6) VentNet has predefined report formats allowing the user to print reports of the system configuration, and monitored ventilator information. VentNet also provides means for archiving data and exporting that data to third party information systems.
- 9D1.7) VentNet displays the alarm status of the monitored ventilators which are indicated by color coded software buttons representing each ventilator. Each software button includes labels allowing the user to designate a patient identification and location. The user may further investigate the specific alarm codes which are active at each ventilator.
- 9D1.8) VentNet can optionally be configured to work with paging systems to allow the remote notification of certain alarm conditions. The user can designate where alarm messages are sent and can modify the conditions under which a ventilator alarm will result in a notice being sent. For each ventilator a primary and a secondary message path can be designated. The user can modify the conditions for notification individually for each monitored ventilator, and for each alarm condition of the ventilator.
- 9D1.9) VentNet incorporates passcode protection to restrict access to functions which interrupt ventilator monitoring or might cause the loss of data.

9D2. PRODUCT AND TECHNICAL SPECIFICATIONS

92D.2.1 Central Station Compliance

9D.2.2 Electrical

9D.2.3 Physical Characteristics

9D.2.4 Environmental

9D.2.5 Operational Characteristics

9D.2.7 Radio-Link Transceivers Operational Characteristics

9D.2.8 Laser Printer Requirements

9D.2.9 Component and System Labels

9D.2.10 Central Station Compliance

This section contains specifications for components of the central station and the bedside station remote radio transceiver. Requirements for the facility provided laser printer are also provided.

9D.2.11 Electrical Characteristics

Central Station External AC Input Voltage/Current

115 Vac, 60 Hz, 5 A (maximum) or
230 Vac, 50 Hz, 2.6 A (maximum)

Remote Radio Transceiver Defibrillation Protection

The remote radio transceiver shall not be damaged by defibrillation and shall return to normal operation within 15 seconds of defibrillation.

9D.2.12 Physical Characteristics

Dimensions

Computer:

21 cm (8.3 in.) x 40.6 cm (16 in.) x 46 cm (18.1 in.)

Monitor:

38.2 cm (15 in.) or 43.2 cm (17 in.) diagonal screen

Uninterruptible Power Supply:

15.0 cm (6.0 in.) x 9.0 cm (3.4 in.) x 33.0 cm (13.1 in.)

Bedside Station Radio Transceiver

12.5 cm (4.92 in.) x 6.7 cm (2.64 in.) x 3.0 cm (1.18 in.)

Weight

Computer

29.5 kg (65 lbs)

Monitor

13.8 kg (30 lbs, 7 oz)

Uninterruptible Power Supply

8.2 kg (18 lbs)

Bedside Station Radio Transceiver

0.18 kg (6.6 oz)

9D.2.13 Environmental

Temperature

Operating

+10° C to +35° C (+50° F to +95° F)

Shipping/Storage (In sealed shipping container)

-40° C to +70° C (-40° F to +158° F)

Relative Humidity**Operating**

30% RH to 80% RH (noncondensing)

Shipping/Storage (In sealed shipping container)

95 % (maximum)

Central Station Ventilation and Cabling Requirements

All components of the central station should have a minimum of 1.5 inches clearance around top, sides, back, and front for ventilation. No central station component should be installed in an enclosed cabinet. A minimum of 4 inches is required behind the computer to accommodate cabling.

9D.2.14 Operational Characteristics**Computer**

Pentium-100 MHz

16 MB RAM

1 GB Hard Drive

3.5-inch Floppy Drive

Hercules Dynamite Video Board

Serial Mouse

101-key Keyboard

Monitor

15 inch or 17 inch diagonal screen

Touchscreen hardware installed

800 x 600 pixel resolution

256 colors

9D.2.15 Hard-wired Interface Characteristics

Selectable EIA-232 or EIA-422

RJ45 interface connector at central station

9-pin D-connector at the bedside station

Radio-Link Transceivers Characteristics**Central Transceiver Transmitter**

Frequency 902 to 928 MHz

RF Output Power +20 dBm (100 mW) minimum

RF Power Adj. > 20 dB range

Settling Time < 100 usec
 Frequency Stability $\pm 0.001\%$
 Modulation Type Direct FM, DDS Synthesized NRZ
 Modulation Rate 62.5 kilobaud (nominal)
 Antennas Omni-directional
 Spectrum Usage Spread spectrum (IAW FCC Par. 15.247)
 FCC CISPR 11 - Class A with exceptions for intentional radiators covered by FCC Part 15, Section 247

Central Transceiver Receiver

Frequency 902 to 928 MHz
 Frequency Spacing 1 kHz
 Settling time 100 usec
 Frequency Stability $\pm 0.001\%$
 Selectivity 180 kHz (3 dB) nominal
 300 kHz (20 dB) nominal
 Sensitivity: -80 dBm (minimum) in 180 kHz bandwidth for 10 dB SNR
 Modulation Type Direct FM, DDS Synthesized NRZ
 Modulation Rate 133 kilobaud
 Diversity Full voting, 2 channels
 Input impedance 2:1 VSWR maximum (50 ohm)
 Host PC Interface Memory-mapped, dual port RAM
 Antennas Omni-directional

Remote Transceiver Transmitter

Frequency 902 to 928 MHz
 RF Output Power +15 dBm nominal, ± 2.0 dB
 RF Power Adj. > 20 dB range
 Settling Time < 300 usec
 Frequency Stability $\pm 0.001\%$
 Modulation Type Direct FM, DDS Synthesized NRZ
 Modulation Rate 133 kilobaud (nominal)
 Frame Length: 30 milliseconds
 Data Rate Instantaneous bandwidth variability
 FCC CISPR 11 - Class B with exceptions for intentional radiators covered by FCC Part 15, Section 247

Remote Transceiver Receiver

Frequency 902 to 928 MHz
 Settling time < 300 usec
 Frequency Stability $\pm 0.001\%$

Selectivity 180 kHz (3 dB) nominal 300 kHz (20 dB) nominal
Sensitivity -90 dBm (minimum) in 180 kHz: bandwidth for 10 dB
SNR
Spurious Rejection 50 dB nominal
Modulation Type 100 kHz deviation NRZ
Modulation Rate 133 kilobaud
Input impedance 2:1 VSWR maximum (50 ohm)

Laser Printer Minimum Requirements

The *VentNet* monitoring system supports printers that are both HPGL/2 and PCL5 compatible with a minimum of 2 megabytes of printer memory such as the Hewlett-Packard LaserJet models 4, 4SI, 4L, 5, 5SI, and 5L printers.

Component and System Labels

There are two labels on the rear panel of the central station computer described as follows.

An identification label showing product title, model, and serial numbers plus agency certifications is affixed on the rear panel of the central station computer by the original manufacturer. This label shows certification compliances at the time the computer was purchased from the manufacturer and is applicable to the computer only. This label also facilitates product traceability through the manufacturer's product records system.

Another identification label showing the system model number is affixed on the rear panel of the central station computer by Nellcor Puritan Bennett. This label shows CSA/NRTL/C certification that is applicable to the VentNet monitoring system as a whole. This certification is based on the Canadian Standard for Electromedical Equipment, C22.2, No. 125 and the Underwriters Laboratories Standard for Medical and Dental Equipment, UL544.

9E. COMPARISON MATRIX

VentNet vs. Spacelabs PCMS and VitalCom Model 1100

*NOTE: THE 7200 VENTILATOR CONNECTS TO THE SPACELABS PCMS VIA
THE FLEXPORT INTERFACE (90436-01)*

Characteristic	VentNet Central Monitoring Station	Spacelabs Patient Care Management System (PCMS) (K913038)	VitalCom Model 1100 Central Monitoring Station (K942147)
Display	SVGA Color Monitor with and without touchscreen	SVGA Color Monitor with and without touchscreen	SVGA Color Monitor with and without touchscreen
Channels	Up to 24 Patients (wireless) Up to 16 Patients (hardwire)	Access of up to 16 Patients (telemetry or hardwire)	8 independent with 2 waveforms per channel; (16 for remote displays)
Hardware	PC based, Pentium, 75 MHz or higher, 16 MB RAM, 1.2 GB HD	CPU based 80486, 50 MHz, 48 MB RAM, 700 MB HD	Mini-tower personal computer 486 or higher.
Hardwire Interface	RS232 or RS422 Interface	Spacelabs Flexport Interface (K903702)	RS232
Radio Transmitter Interface (wireless)	1. Remote Transceiver - Frequency 903 - 920 MHz - Output 50 mW (Max) 2. Central Transceiver - Frequency 903 - 922 MHz - Output 500 mW (Max)	Not Provided	Multiple, Applicable option: 1. Remote Transceiver - Frequency 903 - 920 MHz - Output 50 mW (Max) 2. Central Transceiver - Frequency 903 - 922 MHz - Output 500 mW (Max)
Software Operating System	Microsoft Window 3.11	unknown	VRTX
Ventilator Settings	Provided by the 7200 Series Ventilator	Provided by the 7200 Series Ventilator	not applicable
Patient Data	Provided by the 7200 Series Ventilator	Provided by the 7200 Series Ventilator	not applicable
Ventilator Alarm Settings	Provided by the 7200 Series Ventilator	High/Low Limits Adjustable at the Bedside Monitor, a remote location and at the Central Monitor	not applicable
Individual patient real time alarm status	Status of the ventilator alarms for a selected patient as provided by the 7200 series ventilator.	Patient displayed status in the patient block	ECG, Arrhythmia, and Bedside Monitor alarm status for individual patients
Paging	User selectable for each patient, either no page, autopage to one number, or manual page to a preset number. VentNet uses a hospital paging system using the standard TAP protocol	Not provided	(Optional) Paging via user prompt to hospital paging system, including Zone paging.

Characteristic	VentNet Central Monitoring Station	Spacelabs Patient Care Management System (PCMS) (K913038)	VitalCom Model 1100 Central Monitoring Station (K942147)
Tabular Trends	Future Options	Tabular trends include both settings and monitored patient data	ST and others if available from the Bedside
Graphical Trends	Future Options	Graphical trends of tidal volume and respiratory rate	Pressure (NIBP), and Pleth and others if available from the Bedside
Waveforms	Future Options	Pressure and Flow waveforms are available if the ventilator provides them	ECG, Pressure (NIBP), and Pleth and others if available from the Bedside
Reports	Multiple available, user selectable intervals, automatic print on alarms, and manual requests	User selectable intervals, automatic print on alarms, and manual requests	Multiple available, user selectable intervals, automatic print on alarms, and manual requests
Ventilation Calculations	As provided by the 7200 Series Ventilator	Calculations for minute volume, dynamic & static compliance, dead space volume, dead space to tidal volume ratio, and alveolar ventilation	not applicable
Logs	Alarm, ventilator setting changes, and patient monitoring status	Events Logs	Events Logs

9F. TECHNOLOGICAL CHARACTERISTIC REVIEW

The VentNet Central Monitoring Station is substantially equivalent to the **Spacelabs PCMS Monitor, Model 90845 (K913038)** with the use of the **Spacelabs Flexport Interface, Model 90436-01(K903702)**. The VentNet uses a pentium based personal computer and offers both a hardwire interface and a wireless interface (radio transceivers). This technology is equivalent to the VitalCom Model 1100 systems provided to other manufacturers for communication from bedside monitors to a centralized monitoring station which was determined substantially equivalent in 1995 (K942147). VentNet also utilizes Microsoft Windows 3.11 as it's operating system which is currently being utilized through out the monitoring industry in a variety of products, including the **Zymed Central Station Monitor System, Model T8010 (K951370)**, the **Acuity Central Monitor (K935846)** and the **VMAX Pulmonary / Metabolic System, (K942211)**.

9G. NON-CLINICAL PERFORMANCE DATA REVIEW

The determination of substantial equivalence was based on an assessment of non-clinical performance data. The data includes testing for EMI compatibility and susceptibility, software verification and validation of both the system software performance as well as the operating system software performance, environmental testing and stress testing both at the integration level and the system level. The conclusion drawn from a review of the data indicates that the VentNet is substantially equivalent to the predicate devices.